VIII. May 12, 2014, Letter to Demson Fuller from The Acta Group, *Industrie De Nora S.p.A., December 3, 2013, Meeting Minutes*, resending the January 8, 2014, letter

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May 12, 2014

Via Hand Delivery

Mr. Demson Fuller
U.S. Environmental Protection Agency
Office of Pesticide Programs (MC 7510P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: Industrie De Nora S.pA. December 3, 2013, Meeting Minutes

Dear Mr. Fuller:

This letter and attachment follows up on our March 14, 2014, discussion concerning the above-referenced meeting minutes that were submitted to the U.S. Environmental Protection Agency (EPA) on January 9, 2014, by Industrie De Nora S.p.A.'s (De Nora) former agent, SciReg, Inc., for EPA's review, comment, and concurrence. As you will see, the attached minutes show EPA's pin-punch date stamp. De Nora is very concerned that the minutes appear to have been misplaced by EPA and not delivered to you, preventing your clarification on the issues discussed during the meeting. As De Nora is ready to submit its registration application, your immediate attention to this matter is urgently needed.

To facilitate EPA's review, The Acta Group (Acta) has outlined in this letter the issues and follow-up action items discussed in the minutes for ease of reference. Additionally, we request scheduling a meeting with EPA, with De Nora joining by teleconference, to discuss the follow-up action items. As during the meeting EPA stated it should be able to respond to the issues raised within two weeks, we suggest a meeting/teleconference during the week of May 27, 2014, if that could be scheduled.

From the December 3, 2013, meeting, De Nora and Acta understand that EPA provided the following guidance concerning the proposed registration application, but please confirm:

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- De Nora must register the sodium chloride (NaCl) that will be sold and distributed with the sodium hypochlorite-generating equipment;

- De Nora must address the data requirements for NaCl. De Nora anticipates addressing these data requirements by:

  - Submitting five certificates of analysis for pharmaceutical-grade NaCl for the preliminary analysis; and

  - Citing EPA's database for NaCl, which it describes as complete in its September 1993 *Reregistration Eligibility Decision (RED) Document, Inorganic Halides* and September 2009 *Inorganic Halides Final Work Plan Registration Review* document.

- De Nora must provide a preliminary or 5-batch analysis for the Soleva sodium hypochlorite solution produced by De Nora's equipment and NaCl. From the February 7, 2014, e-mail from Mark Perry, EPA, to Fred Smith, SciReg, we understand that these analyses must be conducted on five batches of both the 0.6 percent and 0.1 percent solutions, with each batch generated using a separate De Nora machine (so five batches total for each of the two solution concentrations).

In addition, De Nora requests EPA's clarification on the following issues, which were discussed at the December 3, 2013, meeting:

- De Nora conducted several efficacy studies in 2012 and 2013 according to EPA's existing efficacy guidelines. Following EPA's December 6, 2013, new guidance specifying that testing must be conducted at the lower certified limit, De Nora has reviewed its studies. Most of the samples in these tests were tested at the lower certified limit or lower, given the concentration decline that occurs during the product's limited shelf life. In addition, Acta notes that in *Reregistration Eligibility Document, Sodium and Calcium Hypochlorite Salts*,[1] EPA states the following:

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[1] EPA, *Reregistration Eligibility Document, Sodium and Calcium Hypochlorite Salts* (Feb. 1992) at 16.

> The Agency has decided to continue its current policy of waiving the product-by-product efficacy data requirement normally levied on sanitizers and disinfectants for sodium and calcium hypochlorite formulations. The Agency has concluded that the published literature data can reasonably be extrapolated to the full range of these products.

In *Na & Ca Hypochlorite Summary Document, Registration Review: Initial Docket,* March 2012, EPA states that there are no outstanding data requirements for these active ingredients. Accordingly, if EPA determines at this time that De Nora must submit efficacy studies, De Nora requests EPA to accept its existing studies, which were completed before EPA published its revised guidance.

- As De Nora states clearly on its proposed label that the Soleva sodium hypochlorite solution is generated in single-use batches, and is effective only for 24 hours (for the disinfectant) or 48 hours (for the sanitizer), De Nora understands that EPA will require it to submit a storage stability study for the Soleva sodium hypochlorite solution but De Nora must conduct the study only for 48 hours. De Nora otherwise will follow the guidelines set forth in OCSPP 830.6317 for Storage Stability. As the sodium hypochlorite solution is stored in a plastic bottle for the 48 hours at room temperature conditions, we do not anticipate that testing will be required under the accelerated conditions in OCSPP 830.6313. Please confirm.

- De Nora understands that in its NaCl registration application, the only data requirements that it must address for the sodium hypochlorite solution are the preliminary analysis and storage stability studies discussed above. Please confirm.

- In response to EPA's request, De Nora will include information about the hardness of the tap water used during the efficacy studies. De Nora also plans to include in its application data that demonstrate that tap water with a range of mineral content/hardness does not affect the generation of the Soleva sodium hypochlorite solution by the De Nora equipment.

- During the December 3, 2013, meeting, Perry stated that he would research the quality control information provided by other similar product

registrations and provide guidance to De Nora in this regard. De Nora appreciates and looks forward to this feedback.

- During the December 3, 2013, meeting, De Nora discussed its interest in having the De Nora system tested with prospective customers in the United States on a limited basis to assess the ease of use of the equipment. Perry stated he would research and provide guidance on this issue as well. De Nora requests EPA to provide it with an Experimental Use Permit (EUP) waiver for this select distribution and evaluation. Please advise what information EPA requires to grant the EUP waiver.

Finally, prior to the follow-up meeting, De Nora will provide EPA with a draft proposed label for review and discussion.

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We hope this issues summary is helpful. We look forward to engaging with EPA to support this exciting new product. Please advise concerning a meeting/teleconference schedule, and as always, please call either me, at (202) 266-5031, or my colleague, Hank Jacoby, at (301) 865-9090, if you have any questions.

Sincerely,

Sheryl Lindros Dolan

Attachment